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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,230	05/23/2005	Naomi Mizusawa	04701/HG	8977

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,230	MIZUSAWA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/20/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the recitation in claim 3 of "an linoleic acid".

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1-10 on 6/20/07 is acknowledged.

Claims 1-10 are being considered on the merits. Claim 11 is withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112/101

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, and 8-10 provide for the use of a bacterium, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-3, and 8-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 9-10 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claims 7 and 9 are confusing in the recitation of "an amount exceeding 10 based on 100 of the substrate linoleic acid". It is unclear what is intended, particularly when using any unidentified bacteria. In addition, the use of the abbreviation "BSA" renders the claim confusing. Moreover, it cannot be readily assessed what constitutes "a complex" between linoleic acid and materials such as BSA, lipid-binding proteins and surfactants or how such a complex is obtained.

Claim 8 is confusing in that the extent of "enriched" and "most" is not delineated with sufficient particularity, even when reading the claims in light of the specification, particularly in the absence of process steps for the method as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of bacteria. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 5 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true,

and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Pariza *et al.*, of record.

The claims appear to be directed to a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells or an enzyme from certain lactic acid bacteria.

Pariza *et al.* disclose a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells, cell extracts or an enzyme from certain lactic acid bacteria. See, e.g. Table II.

Even though the disclosed bacteria are not the necessarily the species as claimed, the claims include cell extracts or enzymes derived therefrom, which would be expected to have the same activity.

Claims 1-4, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kishino *et al.*, of record.

The claims appear to be directed to a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells or an enzyme from certain lactic acid bacteria.

Kishino *et al.* disclose a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells, cell extracts or an enzyme from certain lactic acid bacteria. See, e.g. Table I.

Even though the disclosed bacteria are not the necessarily the species as claimed, the claims include cell extracts or enzymes derived therefrom, which would be expected to have the same activity.

Claims 1-4 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Stanton *et al.* (WO 02/101056)

The claims appear to be directed to a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells or an enzyme from certain lactic acid bacteria.

Stanton *et al.* disclose a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells, cell extracts or an enzyme from certain lactic acid bacteria, including at least *Bidifobacterium breve* and *B. pseudocatelanum*. See, e.g. pages 37-38.

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin *et al.*, of record.

The claims appear to be directed to a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells or an enzyme from certain lactic acid bacteria.

Lin *et al.* disclose a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells, cell extracts or an enzyme from certain lactic acid bacteria. See, e.g. page 28, section 2.2 and Figs, 2 and 3.

Even though the disclosed bacteria are not the necessarily the species as claimed, the claims include cell extracts or enzymes derived therefrom, which would be expected to have the same activity.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton *et al.* (WO 02/101056) taken with Lin *et al.* and Meister *et al.* (U.S. Patent No. 6,200,609)

The claims appear to be directed to a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells or an enzyme from certain lactic acid bacteria.

Stanton *et al.* disclose a process of producing a conjugated fatty acid by treating an unsaturated fatty acid with cells, cell extracts or an enzyme from certain lactic acid bacteria, including at least *Bidifobacterium breve* and *B. pseudocatelanum*. See, e.g. pages 37-38.

The reference differs from the claimed invention in the use of milk as a growth medium. However, Lin *et al.* disclose the use of milk as a culture medium for closely related, if not the same bacteria for the production of conjugated fatty acids.. See, e.g. page 28, section 2.2.

The claimed invention also differs from the references in the use of a preculture step. In any event, the addition of surfactants to bacterial culture media is old and well known in the art as adequately demonstrated by Meister *et al.*, for example. See, e.g., col. 6, paragraph 2, wherein preculture of *Lactobacillus* is carried out containing milk and Tween 80. It is presumed that these materials form a "complex" particularly in the absence of evidence to the contrary.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions such as media parameters for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Stanton *et al.* by culturing further strains of lactic acid bacteria and using media containing milk as taught by Lin *et al.*. and containing materials such as surfactants in addition, as disclosed by Meister *et al.*. for the expected benefit of maximizing the production of useful pharmaceutical products such as conjugated fatty acids, including conjugated linoleic acid, or foods containing these products, including milk or other dairy products fermented with lactic acid bacteria.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
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Art Unit 1651